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Briefing Report to the Chairman,
Special Committee on Aging, U.S.
Senate

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PRESCRIPTION DRUGS

HCEA's Proposed Drug Utilization Review System Ignores Quality of Care Issues



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Program Evaluation and
Methodology Division

B-235298

July 13, 1989

The Honorable David Pryor
Chairman, Special Committee on Aging
United States SenateDTIC
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Dear Mr. Chairman:

Most elderly individuals find that prescription drugs, as well as over-the-counter drugs, are critical to the overall effectiveness of their health care. In a recent report from the Office of the Surgeon General, drugs have been called "an essential component of preventive and curative strategies in health care."¹ There is, however, a negative side to the heavy use of prescription drugs, especially among the elderly. Current research clearly indicates that prescription practices for the elderly need to be specifically targeted to them because of especially adverse drug reactions they may have. These reactions can lead to drug-induced illness, hospitalization, and even death for them, in addition to obviously avoidable and wasteful expenditures for the government and private insurance companies. For example, according to a recent study by the Public Citizen Health Group, each year there are approximately 61,000 older adults with drug-induced Parkinsonism, 32,000 with hip fractures attributable to drug-induced falls, 163,000 with drug-induced memory loss or impaired thinking, and 243,000 hospitalized because of adverse drug reactions.² The economic and human costs of drug-induced illness are significant. The estimated annual price tag in 1983 of drug-related hospitalizations for the elderly and of their post-hospital treatment was \$4.5 billion.³

The Medicare Catastrophic Coverage Act of 1988 (Public Law 100-360) covers outpatient prescription drug costs for an estimated 17 percent of the elderly and provides a mechanism for checking the safety of drugs for all the elderly who use a participating pharmacy. This mechanism is an electronic drug utilization review (DUR) system for prescriptions at the point-of-sale. Such a review is a formal program for assessing data

¹F.G. Abdullah and S.R. Moore (eds.), Proceedings of the Medication Working Group, Surgeon General's Workshop on Health Promotion and Aging (Department of Health and Human Services, March 1988), p. 70.

²Public Citizen Health Group, Worst Pills, Best Pills: The Older Adult's Guide to Avoiding Drug-Induced Death or Illness (New York: Pantheon, 1988).

³Pennsylvania Blue Shield, The Medication Passport and Drug Education Program for Senior Citizens (Pennsylvania Blue Shield, June 1985).

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on drug use against explicit, prospective standards and, as necessary, introducing remedial strategies to achieve some desired end.⁴ A point-of-sale DUR performs this check by linking the prescription-dispensing pharmacy electronically to a central computer drug file and screening for information on possible adverse interactions before the prescription is filled. ←

There are two kinds of DUR. A prospective DUR is a review of the drug therapy at the point-of-sale before the prescription is filled and delivered to the beneficiary. A retrospective DUR is a review of drug therapy carried out some time after the prescription has been filled and delivered to the beneficiary.

Objectives

On October 26, 1988, you requested that we examine the drug utilization review system proposed by the Health Care Financing Administration (HCFA). We examined three broad areas. We have briefed your staff and are providing this briefing report as further clarification of these areas. First, we describe how HCFA plans to implement a drug utilization review (DUR) system. This description can be found in section 2 of this report. Second, we identify major issues associated with the proposed DUR system. These issues are the focus of section 3. Third, we assess the likelihood that HCFA's proposed DUR system will meet the legislative objectives. Our response to this issue is contained in section 4.

HCFA's Proposed DUR System

HCFA, an operating agency of the Department of Health and Human Services (HHS), is the federal agency primarily responsible for implementation and administration of a national Medicare outpatient prescription drug program as prescribed by the act. On May 15, 1989, HCFA issued a draft request for proposal (RFP) that solicited comments on HCFA's plans for implementing a national Medicare outpatient prescription drug program. Having received comments, HCFA is preparing to issue its final RFP. This RFP will cover the structure and implementation of all functions of the program: verification of potential beneficiaries' eligibility for Medicare, determination of whether deductible levels have been reached, screening for potential adverse effects of prescriptions (this is the drug utilization review function), and bill payment. HCFA, along with consultants to the agency, will develop the basic components of that program.

⁴See T.D. Rucker, "Drug Utilization Review: Moving Toward an Effective and Safe Model," in W.E. Fassett and D.B. Christensen (eds.), Computer Application in Pharmacy (Philadelphia: Lea & Febiger, 1986).

All the just-mentioned functions will be carried out by the contractors selected. HCFA's plans for implementing the national Medicare outpatient prescription program call for the system to become operational by January 1, 1991, as mandated in the Medicare Catastrophic Coverage Act of 1988.

The DUR system function proposed by HCFA is very basic with regard to drug information to be produced, since it will only compare drug-to-drug interactions for a limited number of drugs (225 drugs). As detailed in our earlier report to you, drug utilization review systems exist with capabilities far beyond those of the system being proposed by HCFA.⁵ These existing systems include information on drug-to-drug interactions for many more drugs than the number proposed by HCFA, as well as information on maximum and minimum dosage levels, drug allergy reactions, interactions between over-the-counter and prescription drugs, drug-to-diagnosis information, and drug-to-food interactions.⁶

In the proposed HCFA system, data on drug-to-drug interactions will be entered into either a participating pharmacy's computer or a point-of-sale device provided by HCFA to the pharmacy, and then fed electronically to one of three regional drug bill processors (DBPS). At this point, a central computer will screen the current prescription submitted by a pharmacist against the patient's medication profile already entered into the data bank, for possible adverse drug interactions. This information will then be electronically transmitted back to the pharmacy, along with a code for the interaction effect indicating whether prescribing the drug is safe or causes a serious or moderate risk of adverse drug-to-drug interaction.

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Major Unresolved Issues

Our examination of the system proposed by HCFA and discussions with leading health experts lead us to believe that several important issues remain unresolved. A brief discussion follows here, and more detail is given in the text of this report.

It is clear that the success of the national program depends on several factors, including (1) the degree to which the information provided is sufficient to assess drug safety for an elderly population, (2) the quality

⁵Prescription Drugs: Information on Selected Drug Utilization Review Systems, GAO/PEMD-89-18 (Washington, D.C.: May 1989).

⁶Drug-to-diagnosis information compares the drug prescribed against standards for the type and level of drug considered appropriate for treating particular illnesses.

of the program's development and operation of the system, and (3) the extent to which pharmacies participate in the program.

First of all, the minimal DUR system proposed by HCFA is unlikely to be able to provide adequate information on safety. (See pages 20-31.) The Conference Report on the Medicare Catastrophic Coverage Act of 1988 (hereafter known as the Conference Report) states that the conferees expect that all participating pharmacies will review the medication profile of all beneficiaries before filling the prescription, yet the proposed HCFA DUR system will not provide the pharmacist with a complete profile of the patient's medication.⁷ HCFA's system also will not provide information on the patient's diagnosis of illness that can be linked with the drug prescribed. Yet without this diagnosis information, it is difficult, if not impossible, to assess the appropriateness and relative efficacy of drugs for specific diseases in a specific population. This calls into question the quality and completeness of HCFA's proposed data base. Indeed, the one area of complete agreement among physicians, pharmacists, and experts may be the need for establishing and maintaining a sound clinical data base for effective drug utilization reviews. However, this is a highly problematic area in the HCFA program. While the proposed data base will contain information on prescription drugs, it will not include any clinical information pertaining to Medicare beneficiaries, such as use of over-the-counter drugs, drug allergies, and disease/health conditions, and will include only limited information on such things as drug-to-drug reactions, maximum daily dosage, and therapeutic overlap.

In addition, information will not be provided for compound prescriptions—that is, those prescriptions composed of two or more ingredients (compounds). These prescriptions will be treated retrospectively as paper claims. But without the capability to use a prospective approach, the administrative efficiency of electronically capturing these data is lost, and more importantly, potential drug-to-drug interactions will not be known. Overall, we believe HCFA's proposed system is minimal with regard to the completeness of its data base and of the information that will be produced in consequence.

Second, several other major issues exist with regard to HCFA's development and implementation of the DUR system. (See pages 31-35.) For example, it is unclear why HCFA is developing its own DUR system when

⁷U.S. Congress, House of Representatives, Medicare Catastrophic Coverage Act of 1988: Conference Report, Report No. 100-661, 100th Cong., 2nd sess. (Washington, D.C.: U.S. Government Printing Office, 1988).

more comprehensive and well-tested systems already exist. Further, more work is needed in deriving the standards by which retrospective DUR is performed.⁸ Given the medical expertise required for developing these standards, it seems logical that the Secretary of HHS should consult groups better suited to this task than the drug bill processors. In addition, when serious adverse drug-to-drug interactions are identified during the retrospective DUR applied to paper claims, these serious interactions will not be made known to the beneficiary, pharmacist, or physician. Yet, in developing the HCFA system, it would have been useful to provide for such communication since it could help save lives or reduce serious illness, conserve costs to the program, as well as build into the system an important tool for the development of new knowledge about drugs and their applications.

With regard to the operation of HCFA's proposed program, only three months have been allocated for testing the DUR system, which leaves no time to correct any problems other than minor ones. We believe this testing period is unrealistically short: previous experience demonstrates that full operational testing is necessary to identify all the major problems that may face a new system. Further, since each of three contractors is developing an individual system, HCFA is, in effect, testing three systems, not one, along with the interchanges among these systems.

Finally, the extent to which pharmacies participate in the program is extremely important since persons who have their prescriptions filled in nonparticipating pharmacies lose the benefits of a centralized prospective drug utilization review. (See pages 35-36.) It is not clear that HCFA has sufficiently considered incentives and/or other methods to encourage pharmacies to participate.

Likelihood That HCFA's DUR System Will Meet Legislative Objectives

Here, three determinations must be made: (1) whether the system proposed by HCFA can meet its stated objectives and be operational as of the statutorily mandated January 1, 1991, deadline; (2) whether the system, as proposed by HCFA, is consistent with the requirements of the law; and (3) whether a system meeting the congressional requirements can be implemented by January 1991.

⁸Standards are professionally developed expressions of the range of acceptable variations from a norm or criterion.

With regard to the first determination, we believe that the time set aside by HCFA for testing is short and the proposed methods of testing questionable. (See pages 32-33.) A procedure based on a set of "dummy" claims is not sufficient. Realistic operational testing is needed. We believe that HCFA can meet its stated objectives and the congressionally mandated deadline only if it encounters no major problems in testing its DUR system. Based on our experience in reviewing systems under development, we believe it is likely that problems will be uncovered and therefore question whether the HCFA system will be operational by January 1, 1991.

Second, we believe that HCFA's emphasis has been on financial considerations (specifically, bill paying procedures) rather than on the health and safety aspects of drug utilization review. HCFA's proposed DUR system appears to fall short of the expectations for such a system as stated in the law. The goals of the law are to establish a comprehensive DUR that would prevent unnecessary prescribing or dispensing practices, avoid patterns of substandard care, and minimize adverse drug reaction. With respect to whether the contemplated legislative goals will be met by the proposed system, we believe that HCFA could do more to meet these legislative goals.

Third, whether a system meeting the congressional requirements can be implemented by January 1991 depends, once again, on how HCFA intends to interpret the legislation. If the broader definition of the requirements of a prospective DUR system is used, then HCFA clearly cannot design and implement it by January 1, 1991.

All of these issues highlight the importance of resolving three areas of uncertainty: (1) whether a more comprehensive DUR system is necessary to meet the legislative requirements; (2) if so, whether HCFA should pursue a new system or instead choose (or build upon) a DUR system already existing in the public/private sector; and (3) whether the Congress considers the January 1991 deadline as critical.

If the DUR system is to be the one proposed by HCFA, then the results of testing must be closely monitored, and both the Congress and HCFA's top managers should understand the severe limitations of the system's capabilities.

If HCFA is to design a more comprehensive system than the one proposed, then a reconsideration of the feasibility of the current implementation time frame may be necessary.

Finally, if HCFA were to choose one from among the existing comprehensive DUR systems in the public/private sector, then that system must meet the law's requirements, the DUR drug interaction data base must be reviewed and found acceptable by experts, and procurement and implementation must be closely monitored. It is uncertain whether choosing this option at this point in time would make meeting the January 1991 date more feasible, since the time saved due to reduced testing requirements must be balanced against the time necessary to competitively procure an existing system.

Agency Comments

At the request of your staff, we did not obtain comments from the Department of Health and Human Services on a draft of this briefing report. As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution until 30 days from the date of this report. At that time, we will send copies to the Secretary of Health and Human Services and other interested parties and will make copies available to others upon request. If you have any questions or would like additional information, please call me (202-275-1854) or James H. Solomon, Assistant Director (202-275-3593). Other major contributors to this briefing report are listed in appendix I.

Sincerely yours,



Eleanor Chelimsky
Assistant Comptroller General

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Abbreviations

DBP	Drug bill processors
DUR	Drug utilization review
GAO	U.S. General Accounting Office
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
MCCA	Medicare Catastrophic Coverage Act of 1988
MDD	Maximum daily dosage
OTC	Over-the-counter
PDDC	Prime drug data center
POS	Point-of-sale
RFP	Request for proposal

Introduction

In the United States, both prescription and nonprescription drug use increases with increasing age, and the adverse consequences of drug use are more evident in older people.¹

Three fourths of Americans over 65 years of age require one or more prescription drugs. Thirty percent of all prescription drugs used in the United States are taken by people over 65 years of age (approximately three times the rate of the population younger than 65), although this group comprises only about 12 percent of the population.² In addition to using a proportionately larger number of drugs than the general population, the elderly often take the drugs for longer periods.³

There is a negative side to this heavy use of prescription drugs. There are no risk-free drugs, and no single agent is universally effective.⁴ The incidence of adverse drug reactions increases with increased drug use.⁵ An adverse drug reaction is broadly defined as an untoward event that results from a drug administered at a normal or therapeutic dose.⁶ For example, a recent study by the Food and Drug Administration reported that they had received 16 reports of adverse drug reaction for every 100,000 elderly patients compared to 7 reports per 100,000 for the population under age 65.⁷

Current research on prescription practices for the elderly clearly indicates that inappropriate drug prescription can cause adverse drug reactions, which can lead to drug-induced illness, hospitalization and even death, in addition to enormously wasteful expenditures by the government, private insurance companies and, of course, the recipients of these prescriptions. According to a recent study by the Public Citizen Health

¹R.E. Grymponpre et al., "Drug-Associated Hospital Admissions in Older Medical Patients," Journal of the American Geriatric Society, 36 (1988), pp. 1092-1098.

²GAO, Medicare: Prescription Drug Issues, GAO/PEMD-87-20 (Washington, D.C.: July 1987) and D.E. Everitt and J. Avorn, "Drug Prescribing for the Elderly," Archives of Internal Medicine, 146 (1986), pp. 2393-2396.

³P.P. Lamy, "Polymedicine and the Elderly," The Maryland Pharmacist, 63 (1987), pp. 12-15.

⁴P.P. Lamy, "Potential Adverse Effects of Antihypertensive Drugs in the Elderly," Journal of Hypertension, 6 (1988), pp. S81-S85.

⁵J. Williamson and J.M. Chopin, "Adverse Reactions to Prescribed Drugs in the Elderly: A Multi-Center Investigation," Age and Aging, 9 (1980), pp. 73-80.

⁶A.J.J. Wood and J. Feely, "Effect of Age on Sensitivity to Drugs," in K. O'Malley (ed.), Clinical Pharmacology and Drug Treatment in the Elderly (Edinburgh: Churchill Livingstone, 1984), pp. 39-51.

⁷L.A. Tanner et al., "Spontaneous Adverse Reaction Reporting in the Elderly for 1986," Journal of Geriatric Drug Therapy, 3 (1989), pp. 31-54.

Section 1
Introduction

Group, each year there are approximately 61,000 older adults with drug-induced Parkinsonism, 32,000 with hip fractures attributable to drug-induced falls, 163,000 with drug-induced or worsened memory loss or impaired thinking, and 243,000 hospitalized because of adverse drug reactions.⁸ The economic and human costs of drug-induced illness are significant. The estimated annual cost in 1983 of drug-related hospitalizations of the elderly and of their post-hospital treatment was \$4.5 billion.⁹ Elimination of such common drug-related problems would greatly reduce costs for both patients and the government.

Because the elderly often have several chronic conditions that necessitate the use of multiple drugs for longer periods, they are at higher risk for drug-to-drug interactions due to unnecessary, incorrect, or excessive use of medication—including practices such as the use of a drug when it is not indicated, use of several drugs when one would suffice, and concurrent use of drugs that can result in a drug interaction. (See table 1.1.) The problem of adverse drug reactions is further compounded by the increased susceptibility of elderly people to adverse drug reactions due to increased sensitivity (pharmacodynamic effect) and a decreased ability to metabolize and eliminate drugs (pharmacokinetic effect) due to age-related changes that affect the absorption, distribution, metabolism, and excretion of many medications. For example, diseases of the liver and kidneys can profoundly alter the patient's ability to eliminate drugs. If the elimination of a drug is slowed, then this must be compensated for by reducing the dose of the drug.

⁸Public Citizen Health Group, Worst Pills, Best Pills: The Older Adult's Guide to Avoiding Drug-Induced Death or Illness (New York: Pantheon, 1988).

⁹Pennsylvania Blue Shield, The Medication Passport and Drug Education Program for Senior Citizens (Pennsylvania Blue Shield, June 1985).

Section 1
Introduction

Table 1.1: Inherent Problems in Drug Therapy.

Problem	Description
Contraindicated drugs	Use of drugs that worsen the existing condition, such as the use of cold medication containing decongestant by a patient with moderate to severe hypertension
Duplication of drugs	Use of generic and brand name drugs simultaneously
Excessive duration of drug use	Continued use of a drug after the complaint has been resolved
Inappropriate regimen	Use of a complex regimen that cannot be managed by patient or caregiver
Interacting drug	Use of drugs that alter the action of another drug
Misprescribed drug	Use of a drug for an inappropriate indication
Wrong dose	Use of too large or insufficient dosages

Source: Adapted from M. Feinberg, "Polymedicine of the Elderly: Is It Avoidable?" *Pride Institute Journal of Long-Term Health Care*, 8 (1989), p. 8.

The need for prescription drugs for the elderly, the vulnerability of elderly patients to adverse drug effects, and the potential for serious danger associated with inappropriate prescriptions are all addressed in the Medicare Catastrophic Coverage Act (MCCA) of 1988 (Public Law 100-360). MCCA expanded the Medicare program to include coverage for catastrophic medical expenses and a prescription drug benefit for more than 32 million elderly and disabled enrollees.¹⁰ It is estimated that approximately 17 percent of the Medicare-eligible population, or about 5.5 million people, will receive benefits annually at a cost of about \$2.8 billion a year when the drug benefit is fully phased in.¹¹ The Medicare outpatient prescription drug program is designed to be budget neutral, funded solely through payments made by Medicare enrollees.

As a result of MCCA, HCFA is establishing a national Medicare outpatient prescription drug program. This program includes four main functions: verification of potential beneficiaries' eligibility for Medicare, determination of whether deductible levels are reached, screening for potential adverse effects of prescriptions (this is a drug utilization review), and

¹⁰The Medicare program provides two basic forms of insurance protection: Part A, Hospital Insurance, which covers inpatient hospital services, post-hospital care in skilled nursing facilities, intermittent home health care, and hospice care; and Part B, Supplementary Medical Insurance, a voluntary program that covers physicians' services and a variety of other health care services, such as laboratory and outpatient hospital services.

¹¹G.L. Dillingham and J.H. Solomon, "Medicare Outpatient Prescription Drug Benefit," *Pride Institute Journal of Long-Term Health Care*, 8 (1989), pp. 3-14.

billing of enrollees.¹² HCFA, along with contractors and consultants to the agency, will develop the basic functions of that program. All four main functions of the program will be carried out by the contractors selected. HCFA's plans for implementing the national Medicare outpatient prescription program call for the system to become operational by January 1, 1991. The outpatient prescription drug program, including the drug utilization review (DUR) system at the point-of-sale (POS), will be developed to (1) assist pharmacists to improve the quality of care, (2) conserve program funds and individual expenditures, and (3) maintain program integrity—that is, control problems of fraud and abuse. DUR is a formal program for assessing data on drug use against explicit, prospective standards and, as necessary, introducing remedial strategies to achieve some desired end.¹³ A point-of-sale DUR performs these functions at the pharmacy by linking the pharmacy electronically to a central computer drug file and screening for information on possible adverse interactions before the prescription is filled.

There are two kinds of DUR. A prospective DUR is a review of the drug therapy at the POS before the prescription is filled and delivered to the beneficiary. A retrospective DUR is a review of drug therapy carried out some time after the prescription has been filled and delivered to the beneficiary. A retrospective DUR may be focused on one prescription or may look at patterns in prescriptions for one individual, across many individuals, across physicians, or across drugs.

Objectives, Scope, and Methodology

Our three broad study objectives are based on a request received from the chairman of the Senate Special Committee on Aging on October 26, 1988. First, we describe how HCFA plans to implement a drug utilization review system. Second, we identify major issues associated with the system. Third, we assess the likelihood that HCFA's proposed drug utilization review system will meet the legislative objectives of MCCA.

Our main focus in this report is on the drug utilization review system as mandated under MCCA and not on the other functions of the national Medicare outpatient prescription drug program. We did not examine plans for the eligibility or deductibility determination, or the proposed

¹²The Medicare beneficiary will be required to pay a 550 dollar deductible in calendar year 1990 before Medicare begins paying 80 percent of certain drug costs. The deductible level increases and coverage broadens between 1990 and 1993.

¹³See T.D. Rucker, "Drug Utilization Review: Moving Toward an Effective and Safe Model," in W.E. Fassett and D.B. Christensen (eds.), *Computer Applications in Pharmacy* (Philadelphia: Lea & Febiger, 1986).

bill payment system, in any detail. We also did not examine, at this time, the cost of the program.

Our study design involved three major lines of effort.

We conducted an extensive review of the literature on DUR systems from both the conceptual and applied perspectives. We also conducted a detailed review of MCCA and the Conference Report, mapped the provisions required for HCFA, and compared the legislative requirements against HCFA's proposed system to determine the likelihood that HCFA's proposed implementation plan will meet the objectives as stated in the legislation.

Then we examined how HCFA plans to develop and implement the DUR system, including the extent to which it meets the legislative requirements outlined in MCCA and further explained in the Conference Report.¹⁴ We reviewed HCFA documents and held several meetings with various HCFA officials to obtain necessary information.¹⁵ Thus, our information is based, in part, on a draft request for proposal (RFP) issued by HCFA on May 15, 1989, and specific discussions held with HCFA officials. After examining the draft RFP and some of the comments provided by interested parties, we prepared a detailed set of questions, sent it to HCFA for agency review and comments, and conducted in-depth focused interviews with HCFA officials to ensure that we had a thorough understanding of their latest positions on those issues. The public comments received on the draft RFP were not made available to us by HCFA before issuance of this report, but we did receive some of them directly from the authors. We also discussed with HCFA officials their plans for addressing the issues that were identified by various individuals and organizations in response to the draft RFP.

In addition to examining HCFA's proposed DUR system, we also examined some currently available DUR systems in the public/private sectors to determine the capabilities of various DUR systems and their lessons for HCFA. The DUR systems we reviewed were not chosen to be representative of the full universe of available DUR systems; rather, they are systems

¹⁴U.S. Congress, House of Representatives, Medicare Catastrophic Coverage Act of 1988: Conference Report, Report No. 100-661, 100th Cong., 2nd sess. (Washington, D.C.: U.S. Government Printing Office, 1988).

¹⁵As of July 9, 1989, when we finished collecting information, HCFA was still developing plans for its DUR system.

Section 1
Introduction

that we became aware of during the course of our work for the Committee.

We examined the capabilities of these systems by reviewing the available literature and documentation on them, observing their operations during site visits to pharmacies, and discussing these systems with experts.¹⁶ We will not further describe the existing systems in this report but instead will refer to them only as they relate to major issues that we believe need to be addressed by HCFA. We also met with a number of experts in the fields of geriatric medicine and pharmacology, law, and computer systems affiliated with academic, government, and other institutions. We conducted in-depth interviews with these experts to identify issues pertaining to the DUR system proposed by HCFA.

At the request of your staff, we did not obtain comments from the Department of Health and Human Services on a draft of this briefing report. Our work was conducted in accordance with generally accepted government auditing standards.

¹⁶See our report entitled Prescription Drugs: Information on Selected Drug Utilization Review Systems, GAO/PEMD-89-18 (Washington, D.C.: May 1989).

HCFA's Implementation of the Medicare Outpatient Prescription Drug Program

In this section, we describe the Medicare outpatient prescription drug program, with particular emphasis on DUR and DUR-related aspects. This description is drawn from the Medicare Catastrophic Coverage Act of 1988 (including its associated Conference Report) and from information on how HCFA intends to implement the act's provisions. The proposed HCFA system calls for an electronic system for determining a potential beneficiary's eligibility for the Medicare prescription drug program, the beneficiary's progress in meeting the deductible amount, and—through use of a drug utilization review system at the point-of-sale—whether a serious drug interaction is likely. The proposed system also calls for a mechanism for handling paper claims (to be submitted by eligible beneficiaries who use nonparticipating pharmacies).¹ Retrospective reviews and studies to examine issues such as fraud and abuse are also required by HCFA.

Procurement to Establish the Prescription Drug Program

MCCA requires that the Secretary of HHS "establish, by no later than January 1, 1991, a point-of-sale electronic system for use by carriers and participating pharmacies in the submission of information respecting covered outpatient drugs dispensed to Medicare beneficiaries." The carriers are the drug bill processors. The act also authorizes the Secretary to enter into contracts with carriers to perform such activities on a regional basis. In order to facilitate the point-of-sale system, the Secretary is required to provide, upon request, electronic equipment and technical assistance as the Secretary determines may be necessary for the pharmacy to submit claims using an electronic system.

To carry out the legislative mandate, according to the draft RFP, HCFA intends to enter into contracts with three drug bill processors (DBP) on a jurisdictional basis for the implementation and operation of the electronic system for claims processing and drug utilization review for covered outpatient drugs.

Additionally, each of the three DBPs will be expected to serve as a backup operator for one of the other two DBPs. One of the three selected DBPs will function as a prime drug data center (PDDC), in addition to its DBP activities. PDDC will act as a central coordinator for the system. The draft RFP also calls for a system integration contractor to act as HCFA's agent. The functions to be performed by the three DBPs include providing point-of-sale systems, batch and paper transaction processing, bill processing and payment, pharmacy enrollment, drug utilization review,

¹Participation by pharmacies is voluntary.

Section 2
HCFA's Implementation of the Medicare
Outpatient Prescription Drug Program

compliance reviews, audits, computer hardware and software, personnel, training, users' manuals, documentation, and technical assistance.

The computer hardware provided by the DBPs will depend upon what type of computer system already exists in the pharmacies, if any. If a pharmacy wishes to participate in the program and is not computerized, the DBP will provide a point-of-sale (POS) device, which is a small electronic processing box into which the pharmacist can enter prescription data for patients and which transmits these data from the pharmacy to the DBPs for eligibility, deductibility, and prospective DUR screening. Information returned to the pharmacist will be displayed on a POS screen (up to a maximum of two lines of output) indicating whether a potential for adverse drug-to-drug interaction exists and the severity of that interaction. The draft RFP indicates that the DUR data base should contain approximately 225 drug-to-drug interactions that are considered by HCFA as code 1 severity—that is, drug interactions that are of great potential harm to Medicare beneficiaries, are predictable or occur frequently, and are well documented. The entire POS action must take no more than 30 seconds. The estimated cost of each POS device is expected to be approximately 500 dollars. HCFA estimates that 30 percent of the participating pharmacies and almost all dispensing physicians and others who choose to participate in the program will require and receive POS devices.

If a pharmacy already is computerized, it will be required to modify its own computer system to make it compatible with the DBP system. HCFA will provide reduced software costs for participating pharmacies that are already computerized, up to the cost of the POS device.

Enrolling the pharmacies will be the responsibility of the DBPs. Pharmacies (which number about 67,000) will be assigned to one of the three DBP jurisdictions based on their geographical location. In addition, the draft RFP estimates that there are 100,000 physicians, physicians' assistants, and nurse practitioners who are authorized to dispense prescription drugs. If they wish to participate, their offices will be treated by HCFA as participating pharmacies.

The system integrator will develop and execute plans to test and accept all major components of the DBP systems. This includes, among other functions, reviewing all contract deliverables, overseeing the development of hardware and software configurations, telecommunication interfacing, system documentation and disaster recovery, developing

system test procedures and evaluation criteria to certify system performance and compatibility, and conducting system end-to-end tests in order to verify the total operation of the system. In addition, the system integrator will assume the responsibility for the management of the drug bill processing system on a continuing basis. The system integrator will manage the support of the DBPs, consolidate, analyze, and review all reports from the DBPs, manage and control security measures and privacy matters, provide problem and dispute resolution, respond to emergency conditions anywhere in the system, enforce and maintain operational policies and directives, initiate renewal/modifications/enhancements of system components throughout the system's lifetime, and provide hardware and software configuration management and control throughout the system's lifetime.

The act requires the Secretary of HHS to establish a mechanism to identify (1) instances or patterns of unnecessary care or inappropriate prescribing or dispensing practices for covered outpatient drugs, (2) instances or patterns of substandard care with respect to such drugs, and (3) potential adverse reactions. Performing these functions requires that comparison standards be developed. For example, the appropriate dose (maximum/minimum) of a drug for an elderly patient is the standard that the dosage of prescriptions should be compared against. MCCA further states that in establishing such standards, the Secretary "shall incorporate standards from such current authoritative compendia as the secretary may select; except that the secretary may modify such a standard by regulation on the basis of scientific and medical information that such standard is not consistent with the safe and effective use of the drug."

The Conference Report observes that among the compendia that the Secretary is expected to consider for use are

- The United States Pharmacopoeia Dispensing Information, Volume 1 (Drug Information for the Health Care Professional),
- The American Medical Association's Drug Evaluations, and
- American Hospital Formulary Service Drug Information.

The Conference Report states that the conferees expect the Secretary to use only those compendia that base their standards on a review of published scientific and medical information, that provide for a public comment and review process, and that provide adequate assurances that the panelists who establish the standards are free of financial or other conflicts of interest.

System Operation

The Conference Report states: "The conferees expect that participating pharmacists will review the medication profile of beneficiaries for potential adverse reactions before filling prescriptions."

According to HCFA, the DBPs will perform prospective and retrospective DUR activities. To support a prospective DUR program, each DBP should establish and maintain drug interaction data. The data will be used to alert pharmacists about potentially severe drug interactions—that is, to identify the different drug entities that, when taken simultaneously, have the documented potential for producing an adverse effect—and also to detect and report excessive daily doses.

Despite the expectation of the Congress as indicated in the Conference Report, HCFA's RFP does not require a medication profile to be provided or made available to the pharmacists, although such information will reside within the DBP's central computer. In conversations with HCFA officials, we were told that they believe that profiles should not be provided, in order to protect the privacy of the beneficiary.

The act requires the participating pharmacy to offer to counsel or provide information (consistent with state laws respecting the provision of such information) to each Medicare beneficiary on the appropriate use of a drug to be dispensed, including whether there are potential interactions between the drug and other drugs dispensed to the beneficiary. The PDDC, as specified in the draft RFP, will gather and consolidate program-wide data, generate appropriate reports, provide payment calculations to the DBPs, and conduct semi-annual drug-pricing surveys.

Schedule of Events

HCFA's schedule for implementing the system is as follows:

- July 1989, issue final request for proposal;
- October 1989, accept bids;
- January 1990, award contracts;
- September 1990, begin tests on system;
- November 1990, complete testing of system; and
- January 1991, system becomes operational.

Major Issues

The previous section described the intent of MCCA and how HCFA plans to implement a program to meet the law's requirements. In this section, we will describe a number of major concerns about HCFA's planned implementation. For discussion purposes, we have divided these concerns into three categories: (1) drug safety issues, (2) system development and operation, and (3) pharmacy participation issues.

Drug Safety Issues

Drug safety issues are those that relate directly to the amount of information available under HCFA's proposed DUR system to enable the pharmacist to establish the appropriateness of drugs dispensed to the elderly.

Absence of Medication Profiles

As mentioned in the previous section, the Conference Report specifically states that the conferees expect the pharmacist to review the patient's medication profile—that is, the patient's prescription drug history—and make a clinical judgment about the appropriateness of the medication. The alerts—that is, notifications of possible drug interactions—provided to the pharmacist by the electronic DUR system are only advisory and are intended to provide additional information to the pharmacist in making clinical decisions. Yet, HCFA's proposed DUR system will not provide the pharmacist with a complete medication profile, but will only indicate whether a potential drug-to-drug reaction is to be expected and the names of the drug for which the prescription is written and the interacting drug.

HCFA says the reason that no patient medication profiles will be provided to the pharmacies is concern for patient privacy. We also recognize the extremely sensitive nature of the information collected and the need to maintain adequate confidentiality in regard to the data. However, given proper safeguards and appropriate civil and criminal penalties, there is no reason why this program could not be operated just as other federal programs containing sensitive information are, thereby allowing medication profile information to be made available to the pharmacist for the making of proper and informed clinical judgments. We believe HCFA's proposal curtails the information provided by DUR to an extent that makes the system less useful and goes beyond what is necessary to safeguard privacy.

MCCA strongly encourages pharmacists to counsel patients on proper prescription drug use. Without medication profile information, and lacking additional information on the interacting drug—for example, dosage of

the interacting drug, the location and identity of the prescribing physicians, and the date the drug was dispensed—pharmacists will be seriously constrained in their ability to perform patient counseling.

Drug-To-Drug Interactions

The draft RFP states that the data base will contain a list of approximately 225 drug-to-drug interactions that are considered to be of code 1 severity. Code 1 severity indicates drug interactions that are of great potential harm to Medicare beneficiaries, are predictable or occur frequently, and are well documented.¹

HCFA's rationale for their selection of the small number of interactions is based on the reported severity of these reactions in a general population. However, we believe that focusing exclusively on drugs that are dangerous for the general population may overlook drugs that are dangerous for a geriatric population. For example, drug interactions that cause orthostatic hypotension in a general population may not be of great consequence to a healthy 20-year-old male patient.² However, if orthostatic hypotension is experienced by an 80-year-old female osteoporosis patient, the consequence may be a fall and a fractured hip.

The HCFA list of 225 drug-to-drug interactions is also problematic in that it omits some categories of clinically important drug interactions. For example, it excludes

- the "highly protein bound" drugs, including the first generation sulfonylureas (such as phenylbutazone, tolbutamide, and thyroxine) and some, if not most, of the non-steroidal anti-inflammatory drugs (particularly phenytoin and warfarin). A drug in one category may interact with a drug in another category to raise the concentration of the drugs in the blood. For example, phenytoin added to a regimen containing tolbutamide has resulted in both phenytoin toxicity and hypoglycemia.
- Cimetidine, which by virtue of its effect on the metabolism of a number of drugs (notably some of the benzodiazepam drugs) has been described as causing significant interactions with several drugs.

¹ HCFA draft request for proposal, p. C-24.

² Orthostatic hypotension is an excessive fall in blood pressure on assuming a standing position. The condition is not itself a disease but rather a manifestation of abnormalities in blood pressure regulation.

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The need to distinguish the elderly population from other populations is based on the fact that only 7 of the top 25 drugs prescribed to the elderly are included in the HCFA listing of 225 drugs that are to be covered by the drug utilization review. (See table 3.1.) Yet, existing DUR systems have identified many drugs often prescribed for the elderly that are not included in HCFA's list.

Table 3.1: Drugs Most Frequently Prescribed for the Elderly and Their Inclusion in HCFA's Proposed DUR System^a

Rank	Drug	In HCFA's system
1	Lasix	No
2	Lanoxin	Yes
3	Dyazide	Yes
4	Digoxin	Yes
5	Hydrochlorothiazide	Yes
6	Inderal	No
7	Aspirin	Yes
8	Persantine	No
9	Theo-dur	No
10	Nitroglycerin	No
11	Insulin nph	No
12	Coumadin	Yes
13	Prednisone	No
14	Aldomet	No
15	Procardia	No
16	Isordil	No
17	Motrin	No
18	Tylenol with codeine	No
19	Tagamet	Yes
20	Cardizen	No
21	Capoten	No
22	Tenormin	No
23	Lopressor	No
24	Timoptic	No
25	Zantac	No

^aBased on 1986 figures for the drugs dispensed to the elderly—that is, those aged 65 years or older. Source: Adapted from the National Disease and Therapeutic Index (Ambler, Pa.: IMS America, Ltd., 1986) and HCFA draft RFP, item 25C, May 1989.

The incidence of drug interactions may be greater in elderly people due to their decreased abilities to metabolize and excrete drugs. As people age, their ability to metabolize and excrete certain drugs such as digoxin, H₂ antagonists, or benzodiazepines is severely reduced. Since some drug reactions are related to drug dosage, these reactions may be

experienced more frequently in a geriatric population. The likelihood of a drug-to-drug interaction thus generally increases as the age of the user increases. A DUR system for Medicare recipients should include a capability to check drug interactions that would not be likely in the general population but do occur in the elderly population.

It is very important that consulting the drug interaction data files does not result in a high percentage of false-positive alerts, which would frustrate patients, pharmacists, and physicians. A public review of the drug interaction data base by recognized experts in geriatric pharmacology and clinical medicine could minimize this problem.

Over-The-Counter (OTC) Drugs

HCFA does not require information about OTC drugs in the proposed DUR system. OTC drugs are recognized as therapeutic agents if used intelligently and knowledgeably, but they can be hazardous to the elderly. The risk is increased because elderly patients are often given multiple and complex drug regimens. OTC drugs can cause serious adverse reactions due to additive effects and interactions with prescription drugs.³

One of the reasons for being concerned about OTC drugs is that many prescription drugs have recently been switched to OTC status. (See table 3.2.) Pharmaceutical manufacturers are taking action to seek FDA's approval for converting important prescription drugs to OTC status. For example, by 1990, cimetidine will become an OTC drug, to be followed by such drugs as hydrochlorothiazide and propranolol. HCFA has included cimetidine and hydrochlorothiazide in its list of 225 severe potential drug interactions. However, once the drug is changed to an over-the-counter drug, it will no longer be included in the proposed HCFA DUR system. Cimetidine has been documented to interact frequently with many drugs of both the OTC and prescription variety. For example, a typical interaction between theophylline and cimetidine would result in seizures or even death due to theophylline toxicity. If the proposed patient data base does not document the patient's use of OTC drugs (which will increase significantly in the future), the elderly patient is at risk of undetected adverse drug interactions, therapeutic duplications, and other problems.

³P. P. Lamy, "Non-prescription (OTC) Drugs and the Elderly," Maryland Pharmacist, 64 (1988), pp. 9-12.

**Table 3.2: Some Examples of
Prescription Drugs Reclassified as OTCs**

Drug	Indication
Pyrantel pamoate	Pinworms
Diphenhydramine hydrochloride	Night time sleep aid
Hydrocortisone (topical)	Antipruritic
Hydrocortisone acetate (topical)	Antipruritic
Epinephrine hydrochloride	Anorectal vasoconstrictor
Ephedrine sulfate	Anorectal vasoconstrictor
Haloprogin	Antifungal (except Candida)
Miconazole nitrate	Antifungal (except Candida)
Sodium-fluoride rinse	Anticaries
Stannous-fluoride rinse	Anticaries
Stannous-fluoride gel	Anticaries
Acidulated phosphate-fluoride rinse	Anticaries
Brompheniramine maleate	Antihistamine
Cholpreniramine maleate	Antihistamine
Oxymetazoline hydrochloride (topical)	Nasal decongestant
Pseudoephedrine hydrochloride (oral)	Nasal decongestant
Pseudoephedrine sulfate (oral)	Nasal decongestant
Xylometazoline hydrochloride (topical)	Nasal decongestant
Dyclonine hydrochloride	Anesthetic/analgesic

Source: Adapted from P.P. Lamy, "Non-prescription (OTC) Drugs and the Elderly," Maryland Pharmacist, 64 (1988), p. 12.

An explanation offered to us by HCFA as to why OTC drugs are not included in their proposed DUR is that they do not know how to capture this information and that the information would never be up-to-date or complete. Because of its obvious criticality, however, we believe HCFA should research ways of gaining this information. Further, even incomplete information would probably be better than no information at all.

Diagnosis

The interaction between a drug and a disease is a very important source of drug-induced problems, especially in elderly patients. For example, diseases of the liver and kidneys can profoundly alter the patient's ability to eliminate drugs. If the elimination of a drug is slowed, then this must be compensated for by altering the drug regimen by, for example, reducing the dose of the drug.

Collection of patients' diagnostic information has not been included in the draft RFP. HCFA's position is that MCCA does not mandate the provision of the diagnosis on the prescription itself and that the Conference Report prohibits inclusion of the diagnosis as part of the prescription.

HCFA's decision not to include diagnosis information is defensible in that a provision of the Senate bill requiring the use of a diagnosis code on all prescriptions was specifically excluded from the act because the conferees were concerned about the burden on physicians of having to provide diagnosis information on all prescriptions. In order to remove any doubt about HCFA's authority to require inclusion of a diagnostic code on the prescription, further legislation would be necessary.

However, we remain concerned that without diagnosis information it will be very difficult to assess, even by means of a retrospective analysis, the appropriateness and relative efficacy of drugs for specific diseases in specific populations.

One possible way to gain information on diagnosis is by cross referencing separate Medicare data bases. While MCCA does not require physicians to identify diagnosis on prescriptions, physicians are required to include a standard code indicating the patient's diagnosis when filing claim forms for reimbursement for services under Medicare Part B. The Conference Report notes that the diagnosis code information submitted by physicians under Medicare Part B could be used in the future to facilitate drug utilization review by merging Part B data with drug claims data.

There are also problems with the notion of using diagnosis information from Medicare Part B claim forms in lieu of identifying a diagnosis on the prescription. Besides the logistical problems involved in merging different data bases, the Part B claim form may not include complete diagnostic information. For example, a patient who has multiple chronic diseases and is being managed by a single physician may get multiple prescriptions for all his conditions during one visit. Since the physician gets reimbursed based on a visit, there is no incentive to provide a diagnostic code for all conditions currently treated. The physician in this case is most likely to provide the diagnostic code with which he or she is most familiar. Use of such data under these circumstances may lead to erroneous conclusions about likely drug interactions and their safety.

Several computerized programs exist that are used for retrospective DUR without having access to diagnosis information. These programs predict a disease profile from an examination of the patient's medication profile. The mechanism used involves algorithms that recognize "disease markers"—drugs or combinations of drugs that are indicative of the treatment of a specific disease. Through the use of these predictions, prescriptions can be screened for drug-to-disease contraindications. We

believe that HCFA should further examine the use of such programs if it continues its system without physician-supplied diagnoses on prescriptions.

Allergy and Cross Sensitivity

The DUR system proposed in the draft RFP will not monitor prescription drugs against known drug allergy and cross sensitivity in the beneficiaries.¹ Allergies and cross sensitivities represent easily preventable sources of morbidity and mortality, especially in the elderly population.

The experience with the DUR system of the U.S. Naval Pharmacy, San Diego, California, demonstrates the importance of allergy information. Between April 1988 and March 1989, of the approximately 833,000 prescriptions filled in outpatient pharmacies, 178 alerts with a severity rating indicating a life-threatening or potentially life-threatening interaction were based on the patient's allergy to a drug, compared to 74 alerts for drug-to-drug interactions. Of these 178 alerts, the physicians (on being notified by the pharmacist) made immediate changes in 56 cases—compared to only 11 for drug-to-drug interaction cases. Physicians are generally less aware of a patient's drug allergy than they are of other medical information, and they are receptive to changing prescriptions when new information is provided to them.

A patient's allergy information can be maintained as a simple, two-digit code which can be entered by the pharmacist in conjunction with the first claim submission and periodically thereafter. The pharmacist would have to query the patient about allergies and cross sensitivity to enter this information into the data base. We recognize that the collection and maintenance of patients' allergy information may create an administrative burden; however, the benefits are significant and vital to the well-being of the elderly.

Maximum Daily Dosage

The draft RFP specifies a DUR system that will detect prescribed dosages that exceed the maximum daily dosage (MDD) for only 45 drugs. Food and Drug Administration regulations pertaining to labeling for all approved prescription drugs require the manufacturer to provide MDD in product labeling.

¹Drug allergy is defined as the response elicited by an allergen (a substance capable of inducing a specific, acquired alteration in the capability of a human being to react) after an allergic state has been established. A cross sensitivity is a sensitization to a substance induced by exposure to another substance having cross-reacting antigens.

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For those drugs having MDD information included in HCFA's proposed DUR system, the MDD screening function may create a false sense of security for Medicare beneficiaries. The data base will rely on MDDs reported by the manufacturer from clinical trials of the drug. But clinical trials do not generally involve geriatric patients. Manufacturers differentiate the doses required for patients based on height, weight, renal function, and other factors for those drugs with a narrow therapeutic index, but usually this is done in the "dosage requirement" language rather than in the MDD rubric. While the proposed HCFA system may serve as a very gross screening tool for 45 drugs, it will not screen out many of the adverse reactions for the elderly because many of the maximum dosage levels may be high relative to the tolerances of the geriatric population. For example, the maximum daily dose for cimetidine is listed as 2400 milligrams per day. A review of the Physicians' Desk Reference does show a maximum dose of 2400 milligrams per day for the general population. However, many elderly patients have diminished renal function. The recommended daily dosage for patients with impaired renal function is 600 milligram per day. Thus, the data presented in this DUR listing are not tailored to the elderly and could therefore be dangerous for the Medicare beneficiaries.

The HCFA list of drug interactions excludes many very important drugs, such as the antipsychotic agents, diuretics, beta blockers, anticonvulsants, and antidiabetic agents—all of which are potentially toxic, are commonly used by the elderly, and have published prescription (maximum-minimum) limits. Table 3.3 shows which of the 25 prescription drugs used most frequently by the elderly have MDD levels identified by HCFA's proposed DUR.

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Table 3.3: Drugs Most Frequently Prescribed for the Elderly and the Inclusion of Their Maximum Daily Dosages in HCFA's Proposed DUR System^a

Rank	Drug	In HCFA's system
1	Lasix	No
2	Lanoxin	Yes
3	Dyazide	No
4	Digoxin	Yes
5	Hydrochlorothiazide	No
6	Inderal	No
7	Aspirin	Yes
8	Persantine	No
9	Theo-dur	Yes
10	Nitroglycerin	No
11	Insulin nph	No
12	Coumadin	No
13	Prednisone	No
14	Aldomet	No
15	Procardia	No
16	Isordil	No
17	Motrin	No
18	Tylenol with codeine	Yes
19	Tagamet	Yes
20	Cardizen	No
21	Capoten	No
22	Tenormin	No
23	Lopressor	No
24	Timoptic	No
25	Zantac	Yes

^aBased on 1986 figures for drugs dispensed to the elderly—that is, those aged 65 years or older. Source: Adapted from the National Disease and Therapeutic Index (Ambler, Pa.: IMS America, Ltd., 1986) and HCFA draft RFP, item 25C, May 1989.

Therapeutic Overlap

A group of drugs that have the same intended use is categorized as a therapeutic class. A comprehensive DUR system would include a therapeutic classification index for all drugs in the drug file and would be capable of checking the patient's profile for all therapeutic duplicates and alerting the pharmacist of the occurrence. The draft RFP lists only five therapeutic classes.⁵ This provides for therapeutic overlap examination by HCFA for only 9 of the 25 prescription drugs most frequently used by the elderly, as shown in table 3.4. For example, the current therapeutic duplicate list would not reflect that a patient who was taking insulin

⁵HCFA request for proposal, item 25B, p. J-230.

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and tolbutamide is receiving a therapeutic duplicate. Similarly, the system must be able to differentiate between systemic agents and non-systemic agents. For example, the occurrence of a prescription for hydrocortisone (a non-systemic drug) and prednisone (a systemic drug) should not necessarily initiate an automatic duplicate alert.

Table 3.4: Drugs Most Frequently Prescribed for the Elderly and the Inclusion of Their Therapeutic Classes in HCFA's Proposed DUR System^a

Rank	Drug	In HCFA's system
1	Lasix	No
2	Lanoxin	No
3	Dyazide	No
4	Digoxin	No
5	Hydrochlorothiazide	No
6	Inderal	Yes
7	Aspirin	Yes
8	Persantine	No
9	Theo-dur	No
10	Nitroglycerin	No
11	Insulin nph	No
12	Coumadin	No
13	Prednisone	No
14	Aldomet	Yes
15	Procardia	No
16	Isordil	No
17	Motrin	Yes
18	Tylenol with codeine	No
19	Tagamet	Yes
20	Cardizen	No
21	Capoten	Yes
22	Tenormin	Yes
23	Lopressor	Yes
24	Timoptic	No
25	Zantac	Yes

^aBased on 1986 figures for drugs dispensed to the elderly—that is, those aged 65 years or older.

Source: Adapted from the *National Disease and Therapeutic Index* (Ambler, Pa.: IMS America, Ltd., 1986) and HCFA draft RFP, item 25, May 1989.

Serious Drug Interactions Identified in Paper Claims

As discussed in an earlier section, beneficiaries who have their prescriptions filled by nonparticipating pharmacies must submit a paper claim to the DBP for reimbursement or to have the prescription charge counted against their deductible level. The draft RFP states that the DBPs will

enter all paper claims (explicitly identifying them as paper claims), subject them to a drug utilization review, and record problem codes where found. That is, when the DBP receives a paper claim, it will perform a DUR on it, just as it would for a prescription sent electronically by a pharmacy. The difference is that for paper claims there will be a time delay between the point at which the prescription is filled and when the claim is filed, by mail, by the beneficiary.

There is no requirement for the DBP to provide information to the physician, pharmacist, or beneficiary if a serious drug-to-drug interaction is identified during the retrospective processing of a paper claim.⁶ Since some drug-to-drug interactions have latent effects, the physician, pharmacist, and beneficiary may benefit from information generated from DURs of paper claims.

Performing DUR on paper claims is consistent with the legislative mandate, and we do not see the logic behind not notifying the beneficiary and the provider when a serious (code 1) interaction possibility is detected (late though it may be) by the DBP. Providing such information may save lives or reduce serious illness, conserve costs to the program, as well as build into the system an important tool for the development of new knowledge about drugs and their applications.

Compound Prescriptions

Compound prescriptions are those prescriptions composed of two or more ingredients that the pharmacist combines in the pharmacy (as opposed to those that the pharmacist fills from ready-made capsules, tablets, or liquids). A recent study reported the frequency of compound prescriptions in community pharmacies to be 2.5 percent, with a range from 1.5 to 4 percent.⁷ Applying these rates to Medicare prescription drug claims (estimated at 700 million per year), there could be between 10.5 million and 28 million compound prescriptions filled under the Medicare drug provisions, assuming that frequency of compound prescription does not vary by age.

The RFP states that all claims for compound prescription drugs will be treated as paper claims. That means that no prospective DUR will be performed on these compound prescriptions. Without a prospective DUR, the administrative efficiency of electronically capturing these data is lost,

⁶Nor is there any intent on the part of HCFA to make it possible to secure this information from DBPs.

⁷W.A. Parker, "Compounding Interest," *Canadian Journal of Pharmacy*, 121 (1988), pp. 567-569.

and potential drug-to-drug interaction effects for those compounds will not be known.

There is some experience in electronically reviewing compound prescriptions that HCFA may want to consider. For example, pharmacies in California currently submit compounds electronically to the Pharmaceutical Care Network. Adapting a system for electronically processing compound prescriptions could provide the benefits of a prospective DUR to beneficiaries who would otherwise not receive them.

System Development and Operation

Several issues relating to the proper development and operation of the national Medicare outpatient prescription drug program, including the DUR system, are raised in the following paragraphs.

Existing DUR Systems

The RFP calls for the development of a new DUR system, including software. The system being proposed by HCFA is much more limited in scope—it will address drug-to-drug interactions for only 225 drugs—than those DUR systems currently existing in the public/private sectors. Specific components of the HCFA-proposed and alternative DUR systems are discussed later in this section. We are concerned that HCFA, due to lack of experience with DUR and the tight time frame under which it is operating, may not be able to develop, test, and implement a sound system by January 1991.

In a previous report, we identified several DUR systems in the public/private sectors and found that all the attributes of a DUR system as specified in MCCA and the Conference Report are currently available in at least some operating DUR systems.⁸ Given the tight time frame, we believe HCFA's decision to develop its own software is questionable. Several systems already exist that are more comprehensive than HCFA's proposed system and that have been fully tested and in operation for years. Admittedly, these systems provide linkages to only a fraction of the number of pharmacies that the HCFA system would require. Nonetheless, the basic concepts and computer algorithms should be applicable to the HCFA system, and we therefore believe consideration should be given to ways of acquiring the existing technology.

⁸Prescription Drugs: Information on Selected Drug Utilization Review Systems, GAO/PEMD-89-18 (Washington, D.C.: May 1989).

As we have noted, HCFA's DUR system, both prospective and retrospective, as proposed in the draft RFP, falls short of accomplishing the MCCA mandate in a number of critical, clinically significant areas. Several experts we talked to believe that these areas can be adequately covered by incorporating additional functions, such as a more comprehensive prospective DUR (by expanding the data base to include patient's clinical information—such as diseases/health conditions, allergies, and use of OTCs), with little effect on transaction response time, computer connect time, or cost.⁹ We have not made a determination about the precise effect on response time of employing a more comprehensive DUR, but we certainly believe that the addition to the response time would be small (a few seconds more at most). The computer connect time depends, in part, upon the response time and therefore should be only slightly altered by a more comprehensive DUR system. As noted earlier, cost issues were outside the scope of our work, so we cannot at this time give an independent opinion of possible cost increases.

Time to Develop and Test the System

To meet the January 1991 deadline, HCFA will need to master, on a very tight schedule, the electronic aspects of the national Medicare outpatient prescription drug program. Although HCFA has long experience with the Medicare and Medicaid programs, the drug benefit is a new challenge for the agency because of the electronic national outpatient prescription drug program required by the act. And although HCFA officials have expressed confidence that they will be able to establish a system on time, we have concerns regarding how complete and effective the system will be. In part, these concerns arise from the short testing schedule.

The time frame set forth by HCFA to develop, test, and implement software seems unrealistically short. Similar experiences in other government agencies have shown that applications of this type take at least six months to one year from specification development to final product development. Usually, the first generation software requires several generations of revisions to reach a final "satisfactory" product.

We have reviewed testing in a number of different areas in other fields and have found that realistic testing is essential to the identification of problems within technological systems. We are therefore concerned about HCFA's proposal to employ a three-month testing program using

⁹Response time is the interval between the time the pharmacist enters the patient's information into the POS device and the time when the information on eligibility, progress toward meeting deductibility, and presence or absence of drug-to-drug interactions is received back in the POS device.

only dummy prescriptions rather than a true operational test. In addition, HCFA has no contingency plans for dealing with problems that the simplified testing they intend to perform may uncover. There appears to be no room in HCFA's schedule to correct problems found during the testing phase, unless such problems should turn out to be very small and inconsequential ones.

Further, since each DBP will be developing its own system, HCFA is, in effect, testing not one but three systems. It also has to test the interchanges among these systems.

Involvement of Physicians and Pharmacists

The draft RFP describes the DUR program as being under the control of drug bill processors, including the prime drug data center (PDDC). We are concerned that since the DBPs may lack knowledge of prescribing practices and the draft RFP does not provide for adequate involvement of physicians and pharmacists in the DUR program, inappropriate criteria may be set for pharmacy alerts and for interpreting and analyzing the results of retrospective studies.

In order to help ensure that appropriate DUR studies are performed and that the results of these studies are interpreted and used properly, we believe that consideration should be given to having the development of standards for alerts, design of DUR studies, and the analysis of their results overseen by a drug utilization review board. The DUR board could be composed of practicing physicians with geriatric-clinical backgrounds, clinical pharmacologists, pharmacists, pharmaco-epidemiologists, and other individuals with recognized expertise in drug prescribing, drug dispensing, drug utilization review, and medical quality assurance.

Representatives from professional associations—such as the American Medical Association, the American Pharmaceutical Association, the American Society of Hospital Pharmacists, and the American Geriatric Society—could also assist in development of standards or board membership recommendations.

The responsibilities of the DUR board might include providing advice and reviewing the results of development of comprehensive standards to serve as the framework for studying drug use patterns (for example, determinations of when patterns of outliers exist that would indicate inappropriate prescribing practices); determination of types of studies to be conducted; assessments of drug and medical experience data,

including provisions that permit any physician or pharmacist who is being reviewed for possible inappropriate practices the opportunity to offer contrary evidence; periodic evaluation of both the norms employed and program effectiveness; and development and adoption of appropriate intervention strategies to minimize variance between drug-use practice and standards.

Retrospective DUR

The RFP defines retrospective DUR as a "process that occurs after the drug has been dispensed" and requires that such a review be conducted on all claims, both electronic ones submitted by the pharmacies and paper claims submitted by beneficiaries. (It should be noted that a retrospective DUR offers no immediate opportunity to modify the individual patient's therapy at the time of drug purchase, since it occurs some time after the prescription is filled.)

The draft RFP cites various therapeutical problems to be addressed by a retrospective DUR, such as an unlikely combination of drugs, excessive prescriptions, and inappropriate prescribing. These problems can also indicate cases of fraud, abuse, or misuse, as well as other problems.

We see two problems with HCFA's proposed retrospective DUR procedures. First, the retrospective DUR appears to be focused solely on those analyses which might reveal fraud, abuse, or misuse and does not appear to directly address the quality-of-care or drug safety issue. There is also no mention in the draft RFP of the linkage of patient diagnosis information to prescription information. This omission may indicate that appropriateness of drug therapy, a key component of any DUR program, is not included in retrospective DUR. That is, without information on both the prescription and medical information, there is no way to determine from the data base the appropriateness of the care provided.

A second issue regarding retrospective DUR is the establishment of standards against which HCFA will compare the data in searching for fraud, abuse, and misuse. For example, if a physician prescribes particular drugs with unusual frequency, this information will be captured by the DBP's data base and highlighted for review. There may be legitimate differences of opinion over appropriate standards, and in any case, they must be informed, as the legislation states, by medical expertise. Therefore, it is questionable whether the DBPs should be the sole consultant for these standards, as is currently called for in the draft RFP. The National Institute on Aging, the American Medical Association, the

American Pharmaceutical Association, the Pharmaceutical Manufacturing Association, and other relevant professional bodies may be better suited to consult with the Secretary on this task. In any case, provision should be made for their contribution of knowledge and expertise in the development of these standards.

Pharmacy Participation Issues

According to the draft RFP, the DBPs will identify licensed pharmacies and mail enrollment packages to them. There will be an estimated 20,000 to 25,000 pharmacies in each of the three jurisdictions. The DBPs will use trade and professional journals to inform approximately 100,000 authorized dispensing physicians and others about enrollment in the Medicare prescription drug program.

The success of HCFA's program rests, to some extent, on its success in getting a majority of the pharmacies to participate in the program. The value of prospective drug utilization reviews by means of a centralized system is lost at nonparticipating pharmacies, since all their transactions will be handled as paper claims submitted to the drug bill processors by the beneficiary. No prospective DUR will exist in those instances, and the health and safety benefits of DUR will not be available to beneficiaries who patronize a nonparticipating pharmacy. While HCFA expects an 80 to 90 percent pharmacy participation rate in the first year, it is not clear what the basis is for that estimate.

While obtaining business from Medicare patients and the use of DUR for improving the quality of care a pharmacy can offer to patients argue strongly for pharmacy participation, there are many reasons why a pharmacy may be hesitant to participate. One reason is the possible burden this system will place on the pharmacist. For example, there are concerns about the cost and capacity of point-of-sale devices, including telecommunication charges.¹⁰ Other concerns are the length of the response time, software and hardware requirements for existing or future pharmacy computer systems, the types and form of data to be collected by the system, the system's potential to usurp the pharmacists' professional judgement, increased liability, and the frequency of

¹⁰Telecommunication cost is the cost of the time on phone lines that transmit data back and forth between the pharmacy and the drug bill processor. While participating pharmacies are expected to enter prescription data on all claims for all Medicare patients (thus incurring telecommunication costs for all Medicare patients), they will receive a fee for dispensing drugs only for those beneficiaries who have reached their deductible. This latter category is estimated to contain about 16.8 percent of all Medicare patients.

updates on prices to be paid the pharmacists.¹¹ Some pharmacists are concerned by the fact that their existing DUR system contains as much or more information than that being proposed by HCFA. They question why they would want to go to a system that offers less quality of care than the one they have.

At this point, the only material incentives for participation that HCFA offers to the pharmacies are either a POS device for pharmacies that are not currently computerized or its cost equivalent in software modifications for those that must modify their computer systems, and a dispensing fee for prescriptions that are paid for by Medicare. Participating pharmacies will receive \$4.50 for each prescription filled for patients who meet or exceed their deductible level. Nonparticipating pharmacies receive a \$2.50 dispensing fee.

We believe, as does HCFA, that the pharmacy participation rate is critical to the success of the DUR program. Our view, therefore, is that HCFA should not simply delegate this function to the DBPs but rather should remain actively involved. Contingency plans to improve participation rates, including possible incentives, should be considered now so that they can be implemented quickly if needed.

Implications

This section of our report has pointed up some unresolved issues affecting HCFA's implementation of a DUR system. Taking the time needed to resolve these issues may delay the issuance of HCFA's anticipated request for proposal in July and thus the agency's ability to implement its program by the required January 1991 date. These implications are further discussed in section 4.

¹¹ MCCA mandates semiannual pricing updates. Currently prices are updated weekly or biweekly. The industry believes that semiannual updates are not economical for them in that prices rise more often than semiannually.

Likelihood That HCFA's Proposed DUR System Will Meet Legislative Objectives

The question of whether HCFA's proposed DUR system will meet legislative objectives must be answered in three subquestions. The first is whether the system proposed by HCFA can both meet its stated objectives and be operational as of the statutorily mandated January 1, 1991, deadline. The second question is whether the system as proposed by HCFA is consistent with the requirements of the law. The third question is whether a system meeting these requirements can be implemented by January 1991.

The time frame for designing, testing, and implementing HCFA's proposed system is short, just 17 months. There is much to do and little time in which to do it. HCFA personnel have undoubtedly been working hard to assure that their proposed system can be implemented. However, even if no snags are encountered in HCFA's efforts to implement its DUR system, we believe (as noted earlier) that the amount of time HCFA has set aside to test and evaluate the proposed system is probably inadequate. Further, we find the methods envisaged for testing the system unconvincing. (See pages 32-33.)

Based on our experience of reviewing systems development in this and other areas, it seems unlikely that testing the system through a procedure of "dummy" claims, as HCFA proposes to do, will be sufficient to identify all the major problems that may occur. What HCFA is suggesting can be considered, at best, developmental testing. Realistic operational testing is necessary here. But there is no provision within HCFA's proposed time frame for such testing. Further, even if HCFA's developmental testing methods were excellent, there would still be insufficient time between the initiation and completion of testing for any major problems to be rectified. Therefore, the answer to the question of whether HCFA can implement its system by January 1991 depends upon how strongly one believes that no major problems will be encountered during the testing phase. Since testing has not yet occurred, it is uncertain whether HCFA will meet its deadline. However, it is well known that problems do occur in developing new systems, and this raises the question of why HCFA opted for a new rather than an already developed DUR system. Clearly, choosing one of the systems existing in the public/private sector would have at least reduced testing concerns, since these systems have been both tested and in operation for years.

As to the second question of whether HCFA's proposed program is consistent with the requirements of the law calling for a DUR system, HCFA's proposed DUR system appears to fall short of the expectations for such a

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system as stated in the law. The goals of the law are to establish a comprehensive DUR, which would prevent unnecessary prescribing or dispensing practices, avoid patterns of substandard care, and minimize adverse drug reactions. Further, the Conference Report specifically states that it expects that all participating pharmacies will review the medication profile of each beneficiary before filling the prescription, but HCFA's proposed system does not provide for such a profile. We believe that HCFA's program emphasizes bill payments at the expense of drug prescription utilization review. With respect to whether the contemplated legislative goals will be met by the proposed system, we believe, in sum, that HCFA could do more to meet these legislative goals.

With regard to the third question, whether a program meeting the requirements can be operational by January 1991, again much depends on how HCFA intends to interpret the legislation. If the broader definition is used of the requirements of a prospective DUR system, then HCFA clearly cannot design and implement it by January 1991.

All of these issues highlight the importance of resolving three areas of uncertainty: (1) whether a more comprehensive DUR system is necessary to meet the legislative requirements; (2) if so, whether HCFA should pursue a new system or instead choose (or build upon) a DUR system already existing in the public/private sector; and (3) whether the Congress considers the January 1991 deadline as critical.

If the DUR system is to be the one proposed by HCFA, then the results of testing must be closely monitored, and both the Congress and HCFA's top managers should understand the severe limitations of the system's capabilities.

If HCFA is to design a more comprehensive system than the one proposed, then a reconsideration of the feasibility of the current implementation time frame may be necessary.

Finally, if HCFA were to choose one from among the existing comprehensive DUR systems in the public/private sector, then that system must meet the law's requirements, the DUR drug interaction data base must be reviewed and found acceptable by experts, and procurement and implementation must be closely monitored. It is uncertain whether choosing this option at this point in time would make meeting the January 1991 date more feasible, since the time saved due to reduced testing requirements must be balanced against the time necessary to competitively procure an existing system.

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